REMARKS

Applicants have carefully reviewed the Office Action mailed on August 24, 2010. Applicants respectfully traverse (and do not concede) all objections, rejections, adverse statements, and adverse assertions made by the Examiner. Claims 1-2, 4, 9-13, 15-16, 24, 28, 30-32, 34-38, 50, 52, 54, 56-57, 61, 63, 71-74 and 80-87 have been rejected. With this Amendment, claims 28, 30-32, 43, 50, 78-79, and 85-87 have been amended, claims 1-2, 4, 7-24, 26-27, 33-35, 51-52, 61, 69-76, and 80-84 have been canceled without prejudice, and new claims 88-95 have been added. Claims 28, 30-32, 36-37, 43, 50, 53-59, 62-63, 65-66, 78-79, and 85-95 remain pending, of which claims 43, 53, 55, 58-59, 62, 65-66, and 78-79 have been withdrawn from consideration. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections - 35 U.S.C. §103

In paragraph 4 of the Office Action, claims 1-2, 9-13, 15, 24, 50, 52, 54, 56-57, 61, 63, 73-74 and 80-83 were rejected under 35 U.S.C. §103(a) as being unpatentable over Maseda (U.S. Patent No. 6,514,237) in view of Couvillon (U.S. Patent Application Publication No. 2003/0236531). After careful review, Applicants respectfully disagree. While Applicants do not concede the correctness of the rejection, to further advance prosecution in this application in a timely manner, Applicants have canceled claims 1-2, 9-13, 15, 24, 52, 61, 73-74, and 80-83 without prejudice rendering the rejection of these claims moot.

Turning now to claim 50, which recites:

> 50. A balloon catheter for expanding a stent, comprising:
> a catheter shaft adapted for insertion into a body lumen of a patient, said catheter shaft defining an inflation lumen;
> an inflatable balloon disposed about a distal region of said catheter shaft, wherein the interior of said inflatable balloon is in fluid communication with said inflation lumen;
> one or more electrically actuated members disposed in a recess formed in the distal region of said catheter shaft, wherein said one or more electrically actuated members are radially positioned between said elongated shaft and said inflatable balloon such that an inner surface of the one or more electrically actuated members is attached to an outer surface of the catheter shaft and an outer surface of the one or more electrically actuated members is configured to be in contact with an inner surface of the inflatable balloon, wherein, when activated, said one or more electrically actuated members radially expand such that the outer surface

of the one or more electrically actuated members contacts the inner surface of the inflatable balloon and transforms said inflatable balloon from a radially contracted state in which said balloon catheter is more readily inserted into said body lumen of said patient to a first radially expanded state, wherein said inflatable balloon is configured to be further expanded to a second radially expanded state with an inflation media received via the inflation lumen, wherein the second radially expanded state is larger than the first radially expanded state; and

a stent associated with the inflatable balloon, wherein transforming said inflatable balloon from the radially contracted state to the first radially expanded state with the one or more electrically actuated members expands the stent outwardly from a fully crimped state.

While Applicants respectfully disagree with the rejection, Applicants have amended claim 50 to recite a balloon catheter for expanding a stent comprising "one or more electrically actuated members disposed in a recess formed in the distal region of said catheter shaft, wherein said one or more electrically actuated members are radially positioned between said elongated shaft and said inflatable balloon such that an inner surface of the one or more electrically actuated members is attached to an outer surface of the catheter shaft and an outer surface of the one or more electrically actuated members is configured to be in contact with an inner surface of the inflatable balloon, wherein, when activated, said one or more electrically actuated members radially expand such that the outer surface of the one or more electrically actuated members contacts the inner surface of the inflatable balloon and transforms said inflatable balloon from a radially contracted state in which said balloon catheter is more readily inserted into said body lumen of said patient to a first radially expanded state, wherein said inflatable balloon is configured to be further expanded to a second radially expanded state with an inflation media received via the inflation lumen, wherein the second radially expanded state is larger than the first radially expanded state" and "a stent associated with the inflatable balloon, wherein transforming said inflatable balloon from the radially contracted state to the first radially expanded state with the one or more electrically actuated members expands the stent outwardly from a fully crimped state". Support for this amendment can be found in, for example, paragraphs 63, 65, and 70 and Figures 1A-1C of the application as filed. Nothing in Maseda and Couvillon '531 appear to disclose such features.

Maseda appears to disclose incorporating an EAP material (e.g., composite strands 500) in a balloon catheter to induce movements such as wiggling, slithering, twirling, bending,

pulsing, vibrating, rotation, expansion, contraction or elongation. While Maseda does appear to disclose that balloon 118 or other portions of the balloon catheter may include the EAP composite strands, nothing in Maseda appears to disclose the EAP composite strands (cited as the one or more electrically actuated members) disposed in a recess formed in the distal region of said catheter shaft and radially positioned between said elongated shaft and said inflatable balloon such that an inner surface of the composite strands is attached to an outer surface of the catheter shaft and an outer surface of the composite strands is configured to be in contact with an inner surface of the inflatable balloon, as in claim 50.

Further, nothing in Maseda appears to disclose the balloon 118 of Maseda being expanded to a first state by the composite strands and to a second larger state by inflation media or, more specifically, when the composite strips are activated, the composite strips radially expand such that the outer surface of the one or more electrically actuated members contacts the inner surface of the inflatable balloon and transforms said inflatable balloon from a radially contracted state in which said balloon catheter is more readily inserted into said body lumen of said patient to a first radially expanded state, wherein said inflatable balloon is configured to be further expanded to a second radially expanded state with an inflation media received via the inflation lumen, wherein the second radially expanded state is larger than the first radially expanded state. Instead, Maseda appears to merely disclose that EAP stands may be integrated into various segments of the device such that a section of the device expands in a manner which mimics a balloon. However, expanding in a manner to mimic a balloon is clearly not the same or an equivalent of expanding a balloon. Clearly the so-called balloon of Maseda that the EAP stands mimic is not an inflatable balloon or a balloon that would be capable of receiving an inflation media to expand. Notably, balloon 118 appears to merely be inflated with an inflation media.

Nothing in Couvillon '531 appears to remedy these shortcomings of Maseda. In particular, the EAP actuators 110 of Couvillon '531 do not appear to be disposed in a recess formed in the distal region of said catheter shaft and radially positioned between said elongated shaft and said inflatable balloon such that an inner surface of the composite strands is attached to an outer surface of the catheter shaft and an outer surface of the composite strands is configured to be in contact with an inner surface of the inflatable balloon, as in claim 50.

Additionally, nothing in Couvillon '531 appears to disclose an inflatable balloon of Maseda being expanded to a first state by the composite strands and to a second larger state by inflation media or, more specifically, when the composite strips are activated, the composite strips radially expand such that the outer surface of the one or more electrically actuated members contacts the inner surface of the inflatable balloon and transforms said inflatable balloon from a radially contracted state in which said balloon catheter is more readily inserted into said body lumen of said patient to a first radially expanded state, wherein said inflatable balloon is configured to be further expanded to a second radially expanded state with an inflation media received via the inflation lumen, wherein the second radially expanded state is larger than the first radially expanded state. Instead, Couvillon '531 appears to merely disclose a capture device 100 including aperture 103 and one or more electroactive polymer actuators 110 that open and close the aperture 103 based on control signals sent from a control unit. The one or more electroactive polymer actuators 110 appear to be wrapped around the tubular structural element 102 so that they extend from one side of the aperture 103, around the tubular structural element 102, to the opposite side of the aperture 103. However, as can be clearly seen, capture device 100 is clearly not an inflatable balloon that is inflatable with an inflation media and, as such, cannot be considered the claimed inflatable balloon.

Further, nothing in Maseda and Couvillon '531 appear to disclose "a stent associated with the inflatable balloon, wherein transforming said inflatable balloon from the radially contracted state to the first radially expanded state with the one or more electrically actuated members expands the stent outwardly from a fully crimped state", as recited in claim 50.

Moreover, nothing in the cited references appears to provide any reason or motivation to modify the device of Maseda to arrive at the balloon catheter of claim 50. Under KSR, there must be some reason to make the claimed combination. The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

> "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".

(Emphasis added)(see page 14 of the April 30, 2007 decision). The Court further stated:

> a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

(see page 14 of the April 30, 2007 decision). The Office Action states "[i]t would have been obvious to one or ordinary skill in the art to have incorporated the electroactive polymer actuator strips beneath, within or within recesses of the balloon of Maseda or the inner tube 116, and to have oriented them circumferentially as disclosed by Couvillon". Applicants submit that this statement completely lacks the rational underpinnings required to support a legal conclusion of obviousness, as required by *KSR*, and instead, is a mere conclusory statement. Under *KSR*, this conclusory statement clearly cannot support the legal conclusion of obviousness. The Office Action also states "[r]egarding claims 50 ... the balloon of Maseda as modified in view of Couvillon would be able to have a second, fluid expandable state as claimed since the Maseda balloon overlies a sealed fluid pathway opening and because the electroactive conductive polymers can be expanded to varying degrees". However, again, nothing in this statement provides the rational underpinnings required to support a legal conclusion of obviousness, as required by *KSR*.

It appears that Couvillon '531 was merely selected because Maseda failed to disclose all of the elements of claim 50 (which Applicants submit that the combination still fails to do). That is, the only apparent reason for even selecting Couvillon '531 to combine with Maseda appears to come from Applicants' own disclosure, which is clearly improper. Notably, MPEP § 2142 states:

> To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art (emphasis added).

From this, it is apparent that the legal conclusion must be reached on the basis of facts gleaned from the prior art, namely Maseda and Couvillon '531. However, the Office Action has not identified any facts gleaned from Maseda and Couvillon '531 that support the assertions of modifying the device of Maseda with Couvillon '531 to somehow arrive at the balloon catheter of claim 50. As mentioned above, the only apparent reason for making the proposed combination comes from Applicants' own disclosure, which is clearly improper.

For at least the foregoing reasons, claim 50 is believed to be patentable over Maseda and Couvillon '531. For similar reasons and others, claims 52, 54, 56-57, which depend from claim 50 and include additional distinguishing features, are also believed to be patentable over Maseda and Couvillon '531.

In paragraph 5 of the Office Action, claims 1-2, 4, 9-13, 15-16, 24, 28, 30-32, 34-38, 50, 52, 54, 56-57, 61, 63, 71-74 and 80-87 are rejected under 35 U.S.C. §103(a) as being unpatentable over Maseda (U.S. Patent No. 6,514,237) in view of Couvillon (U.S. Patent Application Publication No. 2003/0236445). Applicants respectfully traverse this rejection. While Applicants do not concede the correctness of the rejection, to further advance prosecution in this application in a timely manner, Applicants have canceled claims 1-2, 4, 9-13, 15-16, 24, 34-35, 52, 61, 71-74, and 80-84 without prejudice rendering the rejection of these claims moot.

Turning now to claim 28, which has been amended to recite:

> 28. A medical device comprising
> an elongate body adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis;
> an inflatable balloon disposed about a distal region of the elongate body; and
> an active region comprising a conductive polymer disposed over the elongate body and at least partially beneath the inflatable balloon, wherein said active region is configured to volumetrically expand in when exposed to an electrical potential; and
> a passive deformable member disposed over the elongate body and beneath the inflatable balloon, wherein, when said active region is exposed to said electrical potential, said active region causes said passive deformable member to expand in at least one radial dimension moving at least a portion of the inflatable balloon from a substantially uninflated state to a first expanded state.

While Applicants respectfully disagree with the rejection, Applicants have amended claim 28 to recite "a passive deformable member disposed over the elongate body and beneath the inflatable balloon, wherein, when said active region is exposed to said electrical potential, said active

region causes said passive deformable member to expand in at least one radial dimension moving at least a portion of the inflatable balloon from a substantially uninflated state to a first expanded state". Nothing in Maseda and Couvillon '445 appear to disclose such a feature. For at least these reasons claim 28 is believed to be patentable over Maseda in view of Couvillon '445. For similar reasons, claims 30-32 and 36-38, which depend from claim 28 and include additional distinguishing features, are also believed to be patentable over Maseda in view of Couvillon '445.

Turning now to claim 50, which recites:

> 50. A balloon catheter for expanding a stent, comprising:
> a catheter shaft adapted for insertion into a body lumen of a patient, said catheter shaft defining an inflation lumen;
> an inflatable balloon disposed about a distal region of said catheter shaft, wherein the interior of said inflatable balloon is in fluid communication with said inflation lumen;
> one or more electrically actuated members disposed in a recess formed in the distal region of said catheter shaft, wherein said one or more electrically actuated members are radially positioned between said elongated shaft and said inflatable balloon such that an inner surface of the one or more electrically actuated members is attached to an outer surface of the catheter shaft and an outer surface of the one or more electrically actuated members is configured to be in contact with an inner surface of the inflatable balloon, wherein, when activated, said one or more electrically actuated members radially expand such that the outer surface of the one or more electrically actuated members contacts the inner surface of the inflatable balloon and transforms said inflatable balloon from a radially contracted state in which said balloon catheter is more readily inserted into said body lumen of said patient to a first radially expanded state, wherein said inflatable balloon is configured to be further expanded to a second radially expanded state with an inflation media received via the inflation lumen, wherein the second radially expanded state is larger than the first radially expanded state; and
> a stent associated with the inflatable balloon, wherein transforming said inflatable balloon from the radially contracted state to the first radially expanded state with the one or more electrically actuated members expands the stent outwardly from a fully crimped state.

For similar reasons discussed above, nothing in Maseda appears to disclose a balloon catheter for expanding a stent comprising "one or more electrically actuated members disposed in a recess formed in the distal region of said catheter shaft, wherein said one or more electrically actuated members are radially positioned between said elongated shaft and said inflatable balloon such that an inner surface of the one or more electrically actuated members is attached to an outer

surface of the catheter shaft and an outer surface of the one or more electrically actuated members is configured to be in contact with an inner surface of the inflatable balloon, wherein, when activated, said one or more electrically actuated members radially expand such that the outer surface of the one or more electrically actuated members contacts the inner surface of the inflatable balloon and transforms said inflatable balloon from a radially contracted state in which said balloon catheter is more readily inserted into said body lumen of said patient to a first radially expanded state, wherein said inflatable balloon is configured to be further expanded to a second radially expanded state with an inflation media received via the inflation lumen, wherein the second radially expanded state is larger than the first radially expanded state" and "a stent associated with the inflatable balloon, wherein transforming said inflatable balloon from the radially contracted state to the first radially expanded state with the one or more electrically actuated members expands the stent outwardly from a fully crimped state", as recited in claim 50. Further, nothing in Couvillon '445 appears to remedy the noted shortcomings. For at least these reasons, claim 50 is believed to be patentable over Maseda in view of Couvillon '445. For similar reasons and others, claims 54, 56-57, 63, and 85-87, which depend from claim 50 and include additional distinguishing features, also believed to be patentable over Maseda in view of Couvillon '445.

In paragraph 6 of the Office Action, claim 87 was rejected under 35 U.S.C. §103(a) as being unpatentable over Maseda in view of Couvillon '445, and further in view of Sharrow (U.S. Patent No. 4,793,359). Applicants respectfully disagree. As discussed, previously, claim 50 is believed to be patentable over Maseda in view of Couvillon '445 and nothing in Sharrow appears to remedy the noted shortcomings. For these and other reasons, claim 87, which depends from claim 50 and includes additional distinguishing features, is also believed to be patentable over Maseda in view of Couvillon '445 and Sharrow.

Newly Presented Claims

With this Amendment, Applicants have added newly presented claims 88-95. For similar reasons discussed above, as well as other reasons, claims 88-95 are also believed to be patentable over the cited references.

Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

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